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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/469,637 12/22/99 MOSES

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EXAMINER
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LAHIVE & COCKFIELD LLP  
28 STATE STREET  
BOSTON MA 02109

GITOMER, R	
ART UNIT	PAPER NUMBER

1623

13

DATE MAILED:

06/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
**09/469,637**

Applicant(s)  
**Moses et al.**

Examiner  
**Ralph Gitomer**

Art Unit  
**1623**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jun 8, 2001
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-10, 16-19, 24-27, 31, 34-63, 65, and 104-129 is/are pending in the application.
- 4a) Of the above, claim(s) 35-46, 49, 56-63, and 104-121 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-10, 16-19, 24-27, 31, 34, 47, 48, 50-55, 65, and 122-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_                      20) ☐ Other:

The amendment received 6/8/01 has been entered and claims 1, 4-10, 16-19, 24-27, 31, 34, ~~63~~, 65, 104-129 are currently pending in this application. Claims 1, 4-10, 16-19, 24-27, 31, 34, 47, 48, 50-55, 65, 122-129 are considered here. The claims have been properly renumbered according to Rule 126. The amended title is acceptable. The new abstract must be submitted on a separate page.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30

Claims 1, 4-10, 16-19, 24-27, 31, 34, 47, 48, 50-55, 65, 122-129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,037,138. Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the present claims encompass those of '138.

The above rejection is maintained for reasons of record.

5           The claims as presented are not properly searchable, hence no art is applied. After the following issues under USC 112 are fully and properly addressed, a search will be conducted.

10           Claims 1, 4-10, 16-19, 24-27, 34, 47, 48, 50-55, 65, 122, 124, 126, 128 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while possibly being enabling for specific enzymes and prostate cancer, does not reasonably provide enablement for "a matrix metalloproteinase" or "cancer". The specification does not enable any person skilled in the art to  
15           which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

          It is noted present claims 124, 126, 128 are directed to various cancers such as bladder, renal and lymphoma in general,  
20           and other claims include other tissues, but no such types of cancer of such tissues are enabled by the present specification.

          In claim 1 and all occurrences, "cancer" and "a matrix metalloproteinase" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine  
25           which such cancer or proteinase would work in the instant

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invention. Note that a given organ, for example the kidney, is prone to more than one type of cancer. Also, regarding the claims directed to ~~the~~ a gelatinase~~s~~, it appears in the Tables in the present specification that not all gelatinases are effective  
5 in the claimed invention, only possibly two may be and they are not characterized in any meaningful way.

~~The~~ A matrix metalloproteinase~~s~~ reads on a multitude of Calpains among many other enzymes which are unlikely to work in the claimed invention.

10 "Cancer" reads on basal cell carcinoma to Ewings sarcoma which are unlikely to work in the claimed invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative disorders and compounds  
15 claimed.
2. Amount of direction or guidance presented is insufficient to predict which disorders and substances encompassed by the claims would work.
3. Presence of working examples are only for specific disorders  
20 and substances and extension to other disorders and compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related disorders and substances are not effective for the claimed functions.
- 25 6. Level of predictability of the art is very unpredictable.

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7. Breadth of the claims encompasses an innumerable number of disorders and compounds.

8. The level of one of ordinary skill in this art is variable. In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

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Applicant's arguments filed 6/8/01 have been fully considered but they are not persuasive.

Applicants argue that The Table 3 on page 22 shows various forms of cancer can be detected by the claimed method.

10 It is the examiner's position that Table 3 indicates that bladder, renal, lymphoma, testicular, and pheochromocytoma cannot be detected by the claimed method. In Table 2 on page 21 subjects with prostate cancer had either or both the presence of >150 kDa or 92kDa enzymes of some sort to some extent. No  
15 controls are seen. In Table 3 it would appear rather random if the subjects had either or both of the same enzymes, no predictability is seen. And there are no controls shown in Table 3 either so no statistical significance can be determined.

20 Claims 122-129 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

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In claim 122, a gelatinase is detected (always) but the correlating step regards the presence or absence of gelatinase which has not been determined.

5       Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10       A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened  
15       statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the  
20       statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner  
25       can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

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The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at  
10 [www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business Center for more information.



Ralph Gitomer  
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